UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HOWARD B. SOME,

Plaintiff,

v.

AMERIHEALTH INSURANCE COMPANY OF NEW JERSEY,

Defendant.

No. 1:23-cv-00660

OPINION

APPEARANCES:

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On behalf of Defendant.

O'HEARN, District Judge.

INTRODUCTION

This matter comes before the Court on cross-Motions for Summary Judgment filed by Plaintiff Howard B. Some ("Plaintiff"), (ECF No. 51), and Defendant Amerihealth Insurance Company of New Jersey ("Defendant"). (ECF No. 55). The Court did not hear oral argument pursuant to Local Rule 78.1. For the reasons that follow, Defendant's Motion is **GRANTED** and Plaintiff's Motion is **DENIED.**

I. BACKGROUND

A. Plaintiff's Application

Plaintiff is a participant in, or beneficiary of, a group health insurance policy (the "Plan") governed by the Employee Retirement Income Security Act of 1974 ("ERISA") and issued by Defendant. (Def.'s SOMF, ECF No. 55-1 at ¶ 1; Pl.'s SOMF, ECF No. 61-1 at ¶ 2). On December 22, 2021, Plaintiff's medical provider submitted a request on his behalf for pre-authorization of an autologous hematopoietic stem cell transplant (the "Procedure") for the treatment of his progressive multiple sclerosis ("MS"). (Def.'s SOMF, ECF No. 55-1 at ¶ 20; Pl.'s SOMF, ECF No. 61-1 at ¶¶ 4–7). Defendant denied the request on January 3, 2022, citing that the Procedure was considered experimental or investigational under the terms of the Plan and Medical Policy Number 11.07.01t (the "HSCT Policy"). (Def.'s SOMF, ECF No. 55-1 at ¶ 21; Pl.'s SOMF, ECF No. 61-1 at ¶¶ 10–11). This initial determination was made by Dr. Todd Campbell, one of Defendant's medical directors. (Def.'s SOMF, ECF No. 55-1 at ¶ 21).

Plaintiff appealed this denial on January 25, 2022, and Defendant assigned the appeal for review to another medical director, Dr. Joseph Vizzoni,[1] and an independent third-party reviewer, Dr. David Masiello, through MLS National Medical Evaluation Services. (Def.'s SOMF, ECF No. 55-1 at ¶¶ 24, 26–28; Pl.'s SOMF, ECF No. 61-1 at ¶ 15). Both reviewers upheld the initial determination, concluding that the Procedure was experimental or investigational for the treatment of Plaintiff's progressive MS, and Defendant subsequently sent another denial letter on February 15, 2022.[2] (Def.'s SOMF, ECF No. 55-1 at ¶¶ 30–31; Pl.'s SOMF, ECF No. 61-1 at ¶ 16).

Plaintiff then requested a second-level appeal, which was considered by Defendant's Stage II Medical Necessity Appeals Panel (the "Appeals Panel") at a hearing on March 24, 2022. (Def.'s SOMF, ECF No. 55-1 at ¶¶ 32–33; Pl.'s SOMF, ECF No. 61-1 at ¶¶ 29, 31). The Appeals Panel—which is comprised of a rotating group of Defendant's medical directors and staff, none of whom have had any prior involvement in reviewing the claim—reviewed

[1] While the Parties dispute whether Dr. Vizzoni's review is part of the Administrative Record, (Pl.'s Opp., ECF No. 60 at 31–32; Def.'s Reply, ECF No. 63 at 9–12), the Court need not reach this issue, as his review does not constitute the final determination and therefore, the Court does not rely on it in reaching its decision. *See Klass v. Reliance Standard Life Ins. Co.*, No. 15-6510, 2017 WL 3741005, at *7 (D.N.J. Aug. 29, 2017) (in determining whether a benefits decision is arbitrary and capricious, "a court must focus on the final, post-appeal decision.") (citation omitted). Nevertheless, the Court is inclined to agree with Defendant that the failure to identify Dr. Vizzoni by name is not fatal. *See, e.g., Jacobs, Jr. v. Guardian Life Ins. Co. of Am.*, 730 F. Supp. 2d 830, 850 (N.D. Ill. 2010) (holding substantial compliance with ERISA where plaintiff failed to show harm from lack of reviewer names); *Stemme v. Blue Cross Blue Shield of Kansas City*, No. 11-2635, 2013 WL 12362335, at *4 (N.D. Tex. Feb. 25, 2013) (finding no ERISA violation for failure to reference external reviewers by name absent evidence of prejudice to plaintiff).

[2] The Parties dispute whether Defendant raised a new reason for denial in its February 15, 2022 Letter, that is, that the Procedure was not medically necessary. (Pl.'s SOMF, ECF No. 61-1 at ¶ 16). Because the final decision by the Appeals Panel did not reference medical necessity, the Court need not reach this issue. (Def.'s SOMF, ECF No. 55-1 at ¶ 39; Pl.'s SOMF, ECF No. 61-1 at ¶¶ 35–36).

Plaintiff's case, heard from Plaintiff and his treating physician, and upheld the denial on March 28, 2022, finding that the Procedure was experimental or investigational. (Def.'s SOMF, ECF No. 55-1 at ¶¶ 33–39; Pl.'s SOMF, ECF No. 61-1 at ¶¶ 31–35). In making its determination, the Appeals Panel relied on the following definition of experimental or investigational:[3]

> A drug, biological product, device, medical treatment or procedure which meets any of the following criteria:
>
> - Is the subject of: Ongoing clinical trials;
> - Is the research, experimental, study, or investigational arm of an ongoing clinical trial(s) or is otherwise under a systematic, intensive investigation to determine its maximum tolerated dose, its toxicity, its safety, its efficacy or its efficacy as compared with a standard means of treatment or diagnosis;
> - Is not of proven benefit for the particular diagnosis or treatment of the Member's particular condition;
> - Is not generally recognized by the medical community, as clearly demonstrated by Reliable Evidence, as effective and appropriate for the diagnosis or treatment of the Member's particular condition; or
> - Is generally recognized, based on Reliable Evidence, by the medical community as a diagnostic or treatment intervention for which additional study regarding its safety and efficacy for the diagnosis or treatment of the Member's particular condition, is recommended.

(Pl.'s SOMF, ECF No. 61-1 at ¶¶ 26, 37).

B. Terms of the Plan

Plaintiff's Plan excludes coverage for services determined by Defendant to be experimental or investigational, as defined under its terms. (Def.'s SOMF, ECF No. 55-1 at ¶ 2). Specifically, the Plan states:

> **Experimental or Investigational** means Carrier determines[4] a service or supply is: a) not of proven benefit for the particular diagnosis or treatment of a particular condition; or b) not generally recognized by the medical community as effective

[3] This definition was also used by the external reviewer, Dr. Masiello, in his External Review Report. (Pl.'s SOMF, ECF No. 61-1 at ¶ 26).

[4] Determine is defined as "the Carrier's right to make a decision or determination. The decision will be applied in a reasonable and non-discriminatory manner. (Def.'s SOMF, ECF No. 55-1 at ¶ 6).

> or appropriate for the particular diagnosis or treatment of a particular condition; or c) provided or performed in special settings for research purposes or under a controlled environment or clinical protocol.
>
> Unless otherwise required by law with respect to drugs which have been prescribed for treatment for which the drug has not been approved by the United States Food and Drug Administration (FDA), Carrier will not cover any services or supplies, including treatment, procedures, drugs, biological products or medical devices or any hospitalizations in connection with Experimental or Investigational services or supplies.

(Def.'s SOMF, ECF No. 55-1 at ¶ 4). The Plan then goes on to state, on a subsequent page, that Defendant:

> will apply the following five criteria in determining whether services or supplies are Experimental or Investigational:
>
> a. Any medical device, drug, or biological product must have received final approval to market by the FDA for the particular diagnosis or condition. Any other approval granted as an interim step in the FDA regulatory process, e.g., an Investigational Device Exemption or an Investigational New Drug Exemption, is not sufficient. Once FDA approval has been granted for another diagnosis or condition, use of the medical device, drug or biological product for another diagnosis or condition will require that one or more of the following established reference compendia:
>
> 1. The American Hospital Formulary Service Drug Information; or
> 2. The United States Pharmacopeia Drug Information
>
> recognize the usage as appropriate medical treatment. As an alternative to such recognition in one or more of the compendia, the usage of the drug will be recognized as appropriate if it is recommended by a clinical study or recommended by a review article in a major peer reviewed professional journal. A medical device, drug or biological product that meets the above tests will not be considered Experimental or Investigational.
>
> b. Conclusive evidence from the published peer-reviewed medical literature must exist that the technology has a positive effect on health outcomes; such evidence must include well designed investigations that have been reproduced by non-affiliated authoritative sources, with measurable results, backed up by the positive endorsements of national medical bodies or panels regarding scientific efficacy and rationale;
>
> c. Demonstrated evidence as reflected in the published peer reviewed medical literature must exist that over time the technology leads to improvement in health outcomes (i.e., the beneficial effects outweigh any harmful effects);
>
> d. Proof as reflected in the published peer-reviewed medical literature must exist that the technology is at least as effective in approving health

outcomes as established technology, or is usable in appropriate clinical contexts in which established technology is not employable; and

e. Proof as reflected in the published peer reviewed medical literature must exist that improvements in health outcomes; as defined item c. above, is possible in standard conditions of medical practice, outside clinical investigatory settings.

(Pl.'s SOMF, ECF No. 61-1 at ¶ 25).

C. The HSCT Policy

To assist in evaluating claims, Defendant relies on Medical Policy Bulletins, which are developed using up-to-date medical research and literature.[5] (Def.'s SOMF, ECF No. 55-1 at ¶¶ 7–8). At the time of Plaintiff's application, Defendant's HSCT Policy stated that while autologous hematopoietic stem cell transplants may be medically necessary and therefore covered for some autoimmune disorders, the Procedure is considered experimental or investigational for the treatment of all other autoimmune diseases, including MS, and is therefore not covered under the Plan. (Def.'s SOMF, ECF No. 55-1 at ¶¶ 10–11). The HSCT Policy linked to a list of references, which included 1,170 sources, 45 of which specifically addressed MS. (Def.'s SOMF, ECF No. 55-1 at ¶ 12).

II. PROCEDURAL HISTORY

Following Defendant's second-level review and denial under the Plan and HSCT Policy, Plaintiff filed a Complaint on February 6, 2023, alleging Defendant wrongfully denied benefits under Section 502(a)(1)(B) of ERISA ("Count I"), or—in the alternative—that Defendant

[5] While Plaintiff disputes that Defendant has shown that the Bulletins set forth standards based on up-to-date medical research and literature, (Pl.'s Resp. SOMF, ECF No. 60-1 at ¶ 8), the HSCT Policy itself states "[t]his Medical Policy Bulletin will be reviewed regularly and be updated as scientific and medical literature becomes available." (AR 149, ECF No. 56-1 at 150).

breached its fiduciary duty under Sections 404 and 409 of ERISA ("Count II").[6] (ECF No. 1). On November 14, 2023, following a dispute between the Parties regarding the standard of review and scope of discovery, Magistrate Judge King issued a Discovery and Scheduling Order, concluding that the proper standard of review was "arbitrary and capricious" and allowing a limited amount of discovery beyond the administrative record for exploring potential conflicts of interest. (ECF No. 35).

Plaintiff filed the Motion for Summary Judgment now before the Court on May 13, 2024. (ECF No. 51). Defendant filed its cross-Motion for Summary Judgment on May 14, 2024. (ECF No. 55). Both Parties filed their Oppositions on June 17, 2024, (ECF Nos. 60–61), and Reply Briefs on July 1, 2024. (ECF Nos. 62–63).

III. LEGAL STANDARD

A. Summary Judgment

Courts may grant summary judgment when a case presents "no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a). A genuine dispute of material fact exists only when there is sufficient evidence for a reasonable jury to find for the non-moving party. *Young v. United States*, 152 F. Supp. 3d 337, 345 (D.N.J. 2015) (citing *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). When the Court considers the evidence presented by the parties, "[t]he evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor." *Id.* at 346 (quoting *Anderson*, 477 U.S. at 255).

[6] On November 9, 2023, during an on-the-record discovery hearing, Judge King ruled that Plaintiff was not entitled to proceed with discovery on Count II at that time. (Tr., ECF No. 40 at 11:14–12:13). Therefore, the instant cross-Motions for Summary Judgment are limited to Count I.

The moving party bears the burden of establishing that no genuine issue of material fact remains. *Id.* (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 330 (1986)). A fact is material only if it will affect the outcome of a lawsuit under the applicable law, and a dispute of material fact is genuine if the evidence is such that a reasonable fact finder could return a verdict for the non-moving party. *Id.* (citing *Anderson*, 477 U.S. at 252). The non-moving party, however, must present "more than a scintilla of evidence showing that there is a genuine issue for trial." *Woloszyn v. Cnty. of Lawrence*, 396 F.3d 314, 319 (3d Cir. 2005).

B. ERISA

Section 502(a) of ERISA creates a civil cause of action for plan participants to "recover benefits due to [them] under the terms of [their] plan, to enforce [their] rights under the terms of the plan, or to clarify [their] rights to future benefits under the terms of the plan." 29 U.S.C. § 1132(a); *Fleisher v. Standard Ins. Co.*, 679 F.3d 116, 120 (3d Cir. 2012). "To assert a claim under this provision, a plan participant must demonstrate that 'he or she . . . ha[s] a right to benefits that is legally enforceable against the plan,' and that the plan administrator improperly denied those benefits." *Fleisher*, 679 F.3d at 120 (quoting *Hooven v. Exxon Mobil Corp.*, 465 F.3d 566, 574 (3d Cir. 2006)).

"[A] denial of benefits challenged under § [502](a)(1)(B)] is to be reviewed under a *de novo* standard unless the benefit plan gives the administrator or fiduciary discretionary authority to determine eligibility for benefits or to construe the terms of the plan." *Firestone Tire & Rubber Co. v. Bruch*, 489 U.S. 101, 115 (1989). When the fiduciary has been granted such discretionary authority, courts will review a denial of benefits under an "arbitrary and capricious" or "abuse of discretion" standard. *McLeod v. Hartford Life & Acc. Ins. Co.*, 372 F.3d 618, 623 (3d Cir. 2004) (citing *Firestone Tire & Rubber Co.*, 489 U.S. at 115; *Smathers v. Multi-*

Tool Inc./Multi-Plastics, Inc. Emp. Health & Welfare Plan, 298 F.3d 191, 194 (3d Cir. 2002)); *see also Howley v. Mellon Fin. Corp.*, 625 F.3d 788, 793 n.6 (3d Cir. 2010) (acknowledging that "arbitrary and capricious" and "abuse of discretion" may be used "interchangeably" in the ERISA context) (citation omitted).

Under the abuse of discretion standard, "[the] court is not free to substitute its own judgment for that of the [fiduciary] in determining eligibility for plan benefits." *Cato v. Unum Life Ins. Co. of Am.*, No. 21-10056, 2022 WL 3013085, at *8 (D.N.J. July 29, 2022) (quoting *Doroshow v. Hartford Life & Acc. Ins. Co.*, 574 F.3d 230, 234 (3d Cir. 2009)). Rather, courts will only set aside a plan fiduciary's decision "if it is without reason, unsupported by substantial evidence or erroneous as a matter of law." *McLeod*, 372 F.3d at 623 (citations omitted). As a result, "deference should be given to the lion's share of ERISA claims." *Cato*, 2022 WL 3013085, at *8 (citations omitted). "Substantial evidence" is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Colone v. Securian Life Ins. Co.*, No. 20-18354, 2023 WL 2063337, at *3 (D.N.J. Feb. 17, 2023) (quoting *Fleisher*, 679 F.3d at 121). The Court must ultimately determine "whether there was a reasonable basis for [the fiduciary's] decision, based upon the facts as known to the [fiduciary] at the time." *Id.* (alterations in original) (citation omitted).

It is the plaintiff's burden to demonstrate that they both qualify for the benefits requested and that the administrator's decision to deny those benefits was arbitrary and capricious. *Menes v. Chubb & Son*, 101 F. Supp. 3d 427, 434 (D.N.J. 2015) (citation omitted).

IV. DISCUSSION

A. Count I

The question presented by the Parties' cross-Motions is a narrow one: was it arbitrary and capricious for Defendant to determine that an autologous hematopoietic stem cell transplant for treatment of Plaintiff's MS was experimental or investigational and, therefore, not covered under the terms of the Plan?

Plaintiff argues that Defendant's decision was arbitrary and capricious because it used an incorrect definition of experimental or investigational. (Pl.'s Mot., ECF No. 51-2 at 10). Plaintiff further contends that Defendant improperly relied on the HSCT Policy, which is not part of his Plan. (*Id.* at 10–11). Defendant counters that it applied the correct definition and properly relied on the HSCT Policy to correctly determine that the Procedure was experimental or investigational and therefore not covered. (Def.'s Opp., ECF No. 61 at 8–22). The Parties further dispute whether Defendant had a structural conflict of interest that influenced its decision to deny Plaintiff's claim. (Pl.'s Mot., ECF No. 51-2 at 19–28; Def.'s Opp., ECF No. 61 at 22–40).

For the reasons that follow, this Court finds that Defendant applied the correct standards and that its decision was supported by substantial evidence such that it was not an abuse of discretion. Moreover, any structural conflict of interest was successfully mitigated. Accordingly, Defendant's Motion for Summary Judgment, (ECF No. 55), is granted and Plaintiff's Motion for Summary Judgment, (ECF No. 51), is denied.

(i) Defendant applied the correct definition of experimental or investigational.

The Parties dispute whether Defendant applied the correct definition of "experimental or investigational" when determining that an autologous hematopoietic stem cell transplant to treat Plaintiff's MS was not covered under the Plan. Specifically, Plaintiff argues that (1) the

definition used in the External Review Report and March 28, 2022 Denial Letter differs from the definition stated in the Plan; and (2) Defendant failed to apply five additional criteria that appear on the following page of the Plan. (Pl.'s Mot., ECF No. 51-2 at 10, 13–19; Pl.'s Opp., ECF No. 60 at 13–23; Pl.'s Reply, ECF No. 62 at 5–7). Defendant counters that (1) the definition cited in its External Review Report and March 28, 2022 Denial Letter was "functionally the same" as that found in the Plan; and (2) the additional criteria are not independent definitional elements but rather serve to supplement the primary definition. (Def.'s Opp., ECF No. 61 at 8–10; Def.'s Reply, ECF No. 63 at 5–7). The Court agrees with Defendant as to both points.

First, the Court finds that Defendant applied a definition of experimental or investigational that is functionally equivalent to the definition stated in the Plan.[7] Specifically, the differences in the definition in the External Review Report and March 28, 2022 Denial Letter versus that in the Plan are as follows:

Definition in External Review Report and March 28, 2022 Denial Letter:	**Definition in Plan:**
"Is not of proven benefit for the particular diagnosis or treatment of the Member's particular condition;"	"[N]ot of proven benefit for the particular diagnosis or treatment of a particular condition;"
"Is not generally recognized by the medical community, <u>as clearly demonstrated by Reliable Evidence</u>, as effective and appropriate for the diagnosis or treatment of the Member's particular condition;" "<u>Is generally recognized, based on Reliable Evidence, by the medical community as a diagnostic or treatment intervention for which</u>	"[N]ot generally recognized by the medical community as effective or appropriate for the particular diagnosis or treatment of a particular condition; or"

[7] Moreover, even if the definitions are not functionally equivalent, a procedure is experimental or investigational if it meets *any* one of the criteria. (AR 140, ECF No. 53-1 at 141). Therefore, because the Court finds that there is substantial evidence that using an autologous hematopoietic stem cell transplant to treat progressive MS meets the first two criteria, *see infra* Section IV.A.iii, the Procedure would nevertheless be excluded.

additional study regarding its safety and efficacy for the diagnosis or treatment of the Member's particular condition, is recommended;"	
"Is the subject of: Ongoing clinical trial;" [or] "Is the research, experimental, study or investigational arm of an ongoing clinical trial(s) or is otherwise under a systematic, intensive investigation to determine its maximum tolerated dose, its toxicity, its safety, its efficacy or its efficacy as compared with a standard means of treatment or diagnosis."	"[P]rovided or performed in special settings for research purposes or under a controlled environment or clinical protocol."

(AR 140, ECF No. 56-1 at 141; AR 354–359, ECF No. 56-3 at 4–9; AR 409–410, ECF No. 56-3 at 59–60) (emphasis showing material differences in language).

The first prong applied by Defendant is virtually identical to that in the Plan, as is the second prong. While the second prong adds the phrase, "as clearly demonstrated by Reliable Evidence," the Court finds that this language does not substantively alter the meaning or application of the definition. Rather, it clarifies the type of evidence required to support a determination, which aligns with the Plan's implied standard for evaluating medical community recognition and effectiveness. Turning to the third prong, while the Plan does not have a verbatim equivalent, the Court nevertheless finds that this language is the mirror-image of the second prong and thus consistent with the Plan's framework. Specifically, if a procedure is recognized as needing additional study to establish safety and efficacy for the treatment of a particular condition, it cannot simultaneously be considered effective or appropriate for the treatment of that condition. Finally, the Court agrees with Defendant that describing a procedure as the "subject of ongoing clinical trials" or "under a systematic, intensive investigation" (prongs four and five) is functionally equivalent to stating that it is "provided or performed in special

settings for research purposes or under a controlled environment or clinical protocol." Therefore, the definition applied in the External Review Report and March 28, 2022 Denial Letter is consistent with, and functionally the same as, the definition stated in the Plan.

While Plaintiff argues an additional set of criteria that appear on a subsequent page of the Plan are part of the definition and control, the Court concludes that these criteria are supplementary and do not alter the definition Defendant applied. The Plan is clear that:

> Experimental or Investigational means [Defendant] determines a service or supply is: a) not of proven benefit for the particular diagnosis or treatment of a particular condition; or b) not generally recognized by the medical community as effective or appropriate for the particular diagnosis or treatment of a particular condition; or c) provided or performed in special settings for research purposes or under a controlled environment or clinical protocol.

(AR 140, ECF No. 53-1 at 141) (emphasis added). It then states on the following page that Defendant "will apply the following five criteria in determining whether services or supplies are Experimental or Investigational." (*Id.* at 142). This language and structure indicates that the five criteria on the following page are supplemental and intended to guide the application of the primary definition, rather than replace it.

Moreover, even if Plaintiff is correct that the five criteria are part of the definition, he is unable to show that the Procedure satisfies any of them. Specifically, the first criteria applies to "[a]ny medical device, drug, or biological product . . ." (*Id.*). It is not applicable where a member seeks coverage for a procedure, as is the case here.[8] The remaining four criteria refer to a procedure's safety and effectiveness, as described in "published peer-reviewed medical literature." (*Id.*). However, as discussed further in Section IV.A.iii, the literature supports

[8] While Plaintiff asserts that the drugs *used* in the Procedure are FDA-approved, (Pl.'s Mot., ECF No. 51-2 at 15; Pl.'s Opp., ECF No. 60 at 18), this is insufficient and would lead to illogical results. For example, under Plaintiff's analysis, any procedure that used drugs to induce general anesthesia would be covered because one of the drugs used in the procedure is FDA-approved.

treatment for refractory relapsing MS, not progressive MS. Accordingly, the Court concludes that Defendant did not abuse its discretion and denies Plaintiff's claim that the denial was arbitrary and capricious on this basis.

(ii) Defendant's reliance on the HSCT Policy was proper.

Plaintiff contends that Defendant acted arbitrarily and capriciously by relying on its HSCT Policy, which Plaintiff argues (1) is not explicitly part of his Plan; and (2) fails to analyze or cite any peer-reviewed medical literature explaining why the Procedure is considered experimental or investigational.[9] (Pl.'s Mot., ECF No. 51-2 at 10–12). The Court finds these arguments unpersuasive for several reasons.

First, as Plaintiff concedes, it is well-established that an administrator may develop and rely on a medical policy so long as the policy aligns with the plan's terms and the administrator's discretionary authority. *Montvale Surgical Ctr., LLC v. Aetna Ins. Co.*, No. 12-2874, 2013 WL 2285952, at *6 (D.N.J. May 22, 2013); *see also Emami v. Cigna Health & Life Ins. Co.*, No. 17-9226, 2019 WL 4187700, at *6 (D.N.J. Sept. 3, 2019) (granting summary judgment where administrator's reliance on medical policy was within discretion to interpret plan benefits and establish guidance); *S.M. v. Oxford Health Plans (N.Y.), Inc.*, 94 F. Supp. 3d 481, 508 (S.D.N.Y. 2015) (discretionary language in plan gave administrator right to establish guidelines for benefit determinations); *Stern v. Oxford Health Plans, Inc.*, No. 12-2379, 2013 WL 3762898, at *8–9

[9] Plaintiff also argues that the HSCT Policy does not identify what definition of experimental or investigational was used in formulating the Policy. (Pl.'s Mot., ECF No. 51-2 at 12). However, as outlined in Section IV.A.i, *supra*, the Court finds Plaintiff's arguments regarding the different definitions to be without merit.

(E.D.N.Y. July 17, 2013) (same).[10] Plaintiff attempts to distinguish these cases, arguing that "in each of those cases, the benefit plan documents expressly incorporated the medical policies into the terms of the plan," and further claiming that "the plan documents must include references to the fact that the administrator will [use medical policy bulletins to review claims]." (Pl.'s Opp., ECF No. 60 at 27–28) (emphasis added). However, as Defendant correctly notes, neither this Court nor the Third Circuit has ever held that, in the absence of specific language in a plan referencing the medical policy at issue, reliance on that medical policy constitutes an abuse of discretion, and the Court declines to insert such a requirement here. Rather, the language stating that "Experimental or Investigational means [Defendant] determines a service or supply is . . ." (AR 140, ECF No. 56-1 at 141), clearly states it is within Defendant's discretion, and it should not be required to start from scratch with each claim it reviews. Accordingly, Defendant's reliance on the HSCT Policy is consistent with its role under the Plan, even if it is not explicitly incorporated, and serves as a codification and/or extension of its discretionary authority to define and exclude investigational procedures.

Second, unlike the policy at issue in *Clauss v. Plan*, 196 F. Supp. 3d 463 (M.D. Pa. 2016), the HSCT Policy was based on 1,170 sources, including 45 specifically addressing MS. (Def. Mot.'s, ECF No. 55-2 at 9–10; Att. A, ECF No. 56-5). This extensive body of medical evidence underpins Defendant's determination that the Procedure is experimental or investigational, satisfying the standard of substantial evidence required under ERISA. *See infra*

[10] Plaintiff also relies on *Miller v. American Airlines, Inc.*, 632 F.3d 837 (3d Cir. 2011) to argue that Defendant's use of the HSCT Policy constitutes an impermissible reliance on an extrinsic document that is not part of the Plan. (Pl.'s Mot., ECF No. 51-2 at 11). However, the Court finds *Miller* to be distinguishable because Defendant is not imposing an extra-contractual requirement. Instead, Defendant is exercising its discretion to develop a policy that guides the application of the term experimental or investigational, a practice that aligns with its authority under the Plan. The Policy is merely an extension of the discretion Defendant already holds under the Plan.

Section IV.A.iii. Therefore, Plaintiff's assertion that the Policy lacked sufficient analysis is undermined by the Administrative Record, which demonstrates that Defendant reviewed and incorporated peer-reviewed literature and guidelines in formulating the HSCT Policy.

While Plaintiff contends that these sources are not a part of the Administrative Record, (Pl.'s Opp., ECF No. 60 at 33), the administrative record "consists of that evidence that was before the administrator when he made the decision being reviewed." *McCann v. Unum Provident*, No. 11-3241, 2013 WL 5603913, at *4 (D.N.J. Oct. 11, 2013) (quoting *Mitchell v. Eastman Kodak Co.*, 113 F.3d 433, 440 (3d Cir. 1997)). Here, the HSCT Policy referred to a list of the peer-reviewed articles and medical literature that Defendant referenced in developing the Policy.[11] (AR 171, ECF No. 56-1 at 172). Therefore, the Court finds that these references were before Defendant in the course of making its decision and are fairly included within the Administrative Record.

The Court also finds *Hundley v. Employee Benefit Plan of the Compass Group, Inc.*, No. 19-2366, 2020 WL 2513070 (D. Kan. May 15, 2020) informative here. There, the court found that links to websites that were cited in a plaintiff's second appeal were not part of the administrative record because:

> [T]he citations do not link to data that was contemporaneous with the administrator's review. Instead, they simply bring the web researcher to the present-day websites for the hospitals. Consequently, there is no assurance that a link suggested by the [p]laintiff at the time the appeal was drafted was the same link that was viewed by the plan administrator in reviewing the appeal; nor is the link likely to connect to the same material that the court would access if it were to search the web at the time of this writing. Moreover, these websites are part of the hospitals' promotional and marketing materials and should not be interpreted as representing a comprehensive catalog of routine services that a hospital provides.

[11] Defendant also directed Plaintiff to the electronic, publicly available version of the HSCT Policy with the links to the references embedded in its February 15, 2022 Denial Letter. (AR 363, ECF No. 56-3 at 13).

Id. at *5. Here, in contrast to those in *Hundley*, the links lead to stable, peer-reviewed content that was contemporaneous with Defendant's review. Therefore, these materials should be considered part of the Administrative Record, and the Court concludes that Defendant's reliance on the HSCT Policy was reasonable and does not support a finding of arbitrariness or capriciousness.

(iii) Defendant's decision that the Procedure was experimental or investigational was supported by substantial evidence.

Though discussed at length in Section III.B, it is worth reemphasizing that under the arbitrary and capricious standard, the Court may only overturn Defendant's decision if it is without reason, unsupported by substantial evidence, or erroneous as a matter of law. *McLeod*, 372 F.3d at 623 (citations omitted). It is a deferential standard, and the Court cannot substitute its own judgment for that of the plan administrator, *Lipani v. Cigna Health and Life Ins. Co.*, No. 21-16851, 2023 WL 4237061, at *4 (D.N.J. June 28, 2023) (citations omitted), nor can it decide which study "prevails" in a dispute over medical evidence. *Turner v. Alcoa Inc.*, No. 15-270, 2016 WL 8257672, at *9 (E.D. Tenn. Dec. 29, 2016). Therefore, even in a case like the one here where there is arguably another reasonable interpretation of the medical evidence, the Court must nevertheless defer to Defendant's decision if it is supported by relevant evidence that a reasonable person might accept as adequate. *Colone*, 2023 WL 2063337, at *3 (citation omitted); *see also Wenzel v. Blue Cross Blue Shield of Minn.*, No. 14-4739, 2015 WL 6549594, at *6 (D. Minn. Oct. 28, 2015) (holding administrator's decision need not be the only sensible interpretation and "should not be disturbed even if another reasonable, but different interpretation may be made.") (citation omitted).

Here, the Appeals Panel denied coverage based on its determination that Plaintiff has progressive MS, not treatment-refractory relapsing MS,[12] (AR 392, ECF No. 56-3 at 42), and there is enough relevant evidence that a reasonable person might accept as adequate in the Administrative Record to support that decision. Indeed, even one of the articles upon which Plaintiff relies states that while the Procedure is the standard of care for treatment-refractory relapsing MS, "[p]atients with progressive MS . . . are less likely to benefit." (Ex. 4, ECF No. 51-8 at 10). Additionally, while Plaintiff points to two other studies, (Ex. 2, ECF No. 51-6; Ex. 3, ECF No. 51-7), only one of the studies was actually performed on patients with progressive MS, and even then, it was limited to a mere twelve people. Accordingly, there is enough evidence—or lack thereof—in the Administrative Record that a reasonable person could conclude that the Procedure was not of proven benefit or generally recognized as effective for the treatment of progressive MS. Therefore, the Court concludes that Defendant's determination was not arbitrary and capricious, and there is no basis to disturb the denial of Plaintiff's claim.

[12] While Plaintiff contends that this was a new reason introduced during litigation, (Pl.'s Reply, ECF No. 62 at 8), the Administrative Record demonstrates otherwise. (AR 392, ECF No. 56-3 at 42) ("he doesn't have relapsing/remitting. Rationale – E/I. Not the standard of care.").

(iv) Defendant properly mitigated any structural conflict of interest.[13]

Turning to Plaintiff's argument regarding the alleged conflict of interest and procedural irregularities, the Court notes that such concerns, while relevant, are a single factor to be weighed under the arbitrary and capricious standard. *Fleisher*, 679 F.3d at 122, n.3 (a structural conflict is one factor in the analysis but "not . . . inherently a determinative factor") (citation omitted). A conflict of interest may be mitigated or even "vanish" where "the administrator has taken active steps to reduce potential bias and to promote accuracy." *Metro. Life Ins. Co. v. Glenn*, 554 U.S. 105, 117 (2008) (citation omitted).

Here, Plaintiff asserts that Defendant's dual role as both the plan administrator and the entity responsible for funding benefit payments created a structural conflict of interest that influenced the denial of his claim. (Pl.'s Mot., ECF No. 51-2 at 19–20). However, the Court finds no evidence in the record to support the assertion that this structural conflict had any material impact on the decision-making process based on the steps taken by Defendant to ensure an unbiased and accurate review process. Specifically, Defendant has adopted a multi-level review process, ensuring that each claim is evaluated on its merits by multiple reviewers, both internal and external. (Def.'s SOMF, ECF No. 55-1 at ¶¶ 41–42). Defendant also shields reviewers from certain information regarding expenditures and does not compensate reviewers

[13] Plaintiff's Statement of Material Facts is deficient in that it does not include any of the facts relied on for its argument that Defendant has an inherent conflict of interest, forcing the Court to "comb the record on behalf of Plaintiff's counsel," *Baker v. Hartford Life Ins. Co.*, No. 08-6382, 2010 WL 2179150, at *17 n.1 (D.N.J. May 28, 2010), *aff'd*, 440 F. App'x. 66 (3d Cir. 2011), and depriving Defendant of any opportunity to reply. "Nevertheless, the Third Circuit has sanctioned the practice of excusing a party's strict compliance with [Rule 56.1] where a court is willing to draw out the facts from the party's briefing and evidentiary submissions instead." *Fox v. Bayside State Prison*, No. 14-5344, 2016 WL 589673, at *3 (D.N.J. Feb. 10, 2016) (citing *Boswell v. Eoon*, 452 F. App'x. 107, 111–12 (3d Cir. 2011)). Therefore, although Plaintiff did not strictly adhere to the Rule, the Court will consider the facts referenced in Plaintiff's moving, opposition, and reply briefs, along with the exhibits attached thereto.

based on the number or outcome of claims they review, eliminating financial incentives that may influence decisions. (*Id.* at ¶ 42). Finally, Defendant has implemented an ongoing quality audit program that retrospectively reviews claims and appeals for consistency, quality, and timeliness. (*Id.* at ¶ 43). These are precisely the sort of steps that other courts have considered and found to reduce or eliminate structural conflicts of interest. *See e.g,. Menes*, 101 F. Supp. 3d at 435–36 (conflict handled properly where claims were reviewed individually, financial and claims offices were separated, and reviewers had no incentive to deny claims); *Marsella v. Am. Airlines*, No. 10-01454, 2011 WL 5007212, at *6 (D.N.J. Oct. 20, 2011) (granting summary judgment where conflict was mitigated by independent review and neutral compensation); *Muccino v. Long Term Disability Income Plan*, No. 11-3641, 2012 WL 2119152, at *9–10 (D.N.J. June 11, 2012) (potential bias mitigated by separating claims administrators from financial interests or imposing management checks that penalize inaccurate decisions).

Although Plaintiff points to procedural irregularities, such as the alleged imposition of extrinsic requirements or failure to identify reviewers by name, (Pl.'s Mot., ECF No. 51-2 at 20–28), there must be "a combination of case-specific structural and procedural factors [to] demonstrate that a fiduciary abused its discretion. . . ." *Noga v. Fulton Fin. Corp. Emp. Benefit Plan*, 19 F.4th 264, 276 (3d Cir. 2021) (emphasis added). Here, having found that Defendant mitigated the alleged conflict of interest, the Court need not consider Plaintiff's allegations of procedural irregularities.

Moreover, even if the conflict of interest remained unmitigated, the Court agrees with Defendant that the procedural irregularities Plaintiff points to are immaterial, and there is no indication Plaintiff's request was denied due to bias or improper motive. *See McBurrows v. Verizon*, No. 15-6321, 2019 WL 2432088, at *10 (D.N.J. June 11, 2019) (noting conflict of

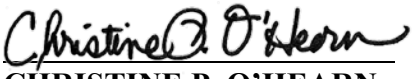
interest due to employer ties but affirming denial where there was no evidence of suspect decision-making and decision was supported by evidence). Accordingly, Plaintiff's argument on this point does not alter the conclusion that Defendant acted within its discretion.

B. Count II

Turning to Defendant's argument that Plaintiff is not entitled to proceed with discovery on Count II because it was dismissed and this Court's decision as to the claims on Count I therefore disposes of this case in its entirety, (Def.'s Opp., ECF No. 61 at 40–41; Def.'s SOMF, ECF No. 55-1 at ¶ 50), the Court observes that, consistent with her authority as a magistrate judge, Judge King's decision was limited and applied only as to the scope of discovery on Count I. *See, e.g., EEOC v. City of Long Branch*, 866 F.3d 93, 98–99 (3d Cir. 2017) (outlining the role of magistrate judges in dispositive vs. nondispositive motions). Without consent of the Parties, the Magistrate Judge could not have, and did not, dispose of the claim on its merits. Therefore, because the District Judge has not entered an order dismissing Count II, nor was a motion to dismiss filed, Count II remains pending. Further, as Defendant did not further substantively brief the merits of the claim in Count II, this Court will not address that claim in the context of this Motion. Rather, the parties shall have a conference with the Magistrate Judge to discuss Count II and whether and how discovery shall proceed now that the Court has disposed of the pending summary judgment motions as to Count I.

CONCLUSION

For the foregoing reasons, Defendant's Motion for Summary Judgment, (ECF No. 55), is **GRANTED** and Plaintiff's Motion for Summary Judgment, (ECF No. 51), is **DENIED**. An appropriate Order accompanies this Opinion.



CHRISTINE P. O'HEARN
United States District Judge